DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-07-04

November 30, 2006

Rolando J. Castillo, President
C. R. D. Group, Inc.
7289 NW 78th Terrace
Medley, Florida 33166

Dear Mr. Castillo:

We inspected your seafood processing and importer establishment, located at 7289 NW 78th Terrace on September 25 and October 2, 2006. We found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123), and the Current Good Manufacturing Practice regulation for foods, Title 21, Code of Federal Regulations, Part 110 (21 CFR 123 & 110). In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fish or fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). The specific requirements for imported fish and fishery products are set out in 21 CFR 123.12. As an importer of fish or fishery products, you must operate in accordance with the requirements of Part 123. In accordance with 21 CFR 123.12(d), there must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with 21 CFR 123. If assurances do not exist that the imported fish or fishery products have been processed under conditions equivalent to those required of domestic processors under 21 CFR Part 123, the fish or fishery products will appear to be adulterated under Section 402(a)(4) of the Act, 21 U.S.C. §342(a)(4).

Accordingly, your crabmeat, mahi-mahi, scombroid-forming species, stone crab claws, sushi grade fish fillets, grouper and snapper are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation and the Fish and Fisheries Products Hazards & Controls Guidance through links in FDA's home page at www.fda.gov.

Your significant violations were as follows:

Domestic:

1. You must conduct or have conducted for you a hazard analysis for each kind of fish and fishery product that you produce to determine whether there are food safety hazards that are reasonably likely to occur and you must have and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a), and (b). However your firm does not have a HACCP plan for:

    a. Refrigerated canned pasteurized crabmeat and Refrigerated cooked ready to eat crabmeat to control the food safety hazard of pathogen growth and toxin formation, specifically Clostridium botulinum.
    b. Refrigerated vacuum packaged mahi-mahi to control the food safety hazard of scombrotoxin formation (histamines) and Clostridium botulinum.

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). A critical limit is defined in 21 CFR 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for

    a. Scombroid-forming species lists a critical limit, "Random probe check internal temperature of fish to ensure proper temperature of 40deg F", at the receiving critical control point that is not adequate to control scombrotoxin formation.

    b. Scombroid-forming species list a critical limit, "Random probe check internal temperature of fish (40deg F) as it comes out of the coolers" at the storage critical control point that is not adequate to control scombrotoxin formation.

FDA currently recommends that secondary processors, such as yourself, to ensure that the histamine producing fish are handled in a safe manner. If you purchase scombroid toxin forming species from other processors or brokers, you must ensure that the fish are consistently maintained at safe temperatures at or below 40°F during transport to your firm. You should monitor transport temperatures by a means that is capable of continuously recording cooler temperatures throughout extended transit periods (i.e, greater than 4 hours) or if product is received on ice or cooling medium by assuring that the goods are completely surrounded in ice or cooling media at receipt. We strongly suggest you refer to Chapter 7 of the Fish and Fisheries Products Hazards and Control Guidance (Third Edition) for specific recommendations for controls, monitoring procedures, and corrective actions.

3. You must have a HACCP plan that, at a minimum, lists monitoring procedures and their frequency for each critical control point, to comply with 21 CFR 123.6 (c) (4). However, your firm's HACCP plan for stone crab claws list monitoring procedures at the storage critical control point that are not adequate to control pathogen growth and toxin formation in that the monitoring procedures do not address "how" the hazard will be controlled, "who" will control the hazard, and the frequency thereof.

4. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b) and (c)(7). However, your firm did not record monitoring observations at the receiving critical control point to control histamine formation listed in your HACCP plan for scombroid species.

5. Your HACCP plan for stone crabs and scombroid species must provide for a record keeping system that documents the monitoring of the critical control points as required by 21 CFR 123.6(c)(7). However, your HACCP plan for:

   - stone crabs fails to provide a recordkeeping system for any of the critical control points.

   - scombroid species fails to provide a recordkeeping system for the storage critical control point.

6. You must maintain sanitation control records that, at a minimum, document monitoring and corrections set out in 21 CFR 123.11(b), to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records for Safety of water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice; Condition and cleanliness of food contact surfaces; Prevention of cross-contamination from insanitary objects; Maintenance of hand washing, hand sanitizing, and toilet facilities; Protection of food, food packaging material, and food contact surfaces from adulteration; Proper labeling, storage and use of toxic compounds; Control of employee health conditions; and Exclusion of pests from the food plant required for the processing of ready to eat sushi grade fish fillets.

7. You must monitor sanitation conditions and practices during processing with sufficient frequency to ensure compliance with current good manufacturing practice requirements in 21 CFR Part 110, to comply with 21 CFR 123.11(b). However, your firm did not monitor Condition and cleanliness of food contact surfaces and Prevention of cross-contamination from insanitary objects with sufficient frequency to ensure compliance with the current good manufacturing practice requirements in 21 CFR Part 110 as evidenced by:

a. The work tables were not sanitized prior to processing fish. This deviation was also noted during the previous inspection conducted on September 22, 23 and 28, 2005.

b. Worker did not wash and sanitize hands or changing disposable gloves after handling insanitary objects while cutting and handling tuna loins to be used for ready to eat sushi. This deviation was also noted during the previous inspection conducted on September 22, 23 and 28, 2005.

Imports:

8. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However your firm did not perform an affirmative step for mahi-mahi, grouper, and snapper manufactured by [redacted] grouper and snapper manufactured by [redacted] and stone crab claws manufactured by [redacted]

We may take further action if you do not promptly correct these violations. For instance, we may take further action to refuse admission of your imported fish or fishery products under Section 801(a) of the Act (21 U.S.C. §381(a)), including placing them on "detention without physical examination," seize your product(s) and/or enjoin your firm from further violating the Act.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You should include in your response documentation, such as HACCP and importer verification records, records that document the performance and results of your firm's affirmative steps, HACCP and verification records associated with your activities as a domestic processor, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

This letter may not list all the violations at your facility. You are responsible for ensuring that your seafood importer and processing establishment operates in compliance with the Act and the seafood HACCP regulation (21 CFR Part 123). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations for the fish or fishery products that you import into the United States.

Please send your reply to the Food and Drug Administration, Attention: Brant M. Schroeder, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issues in this letter, please contact Mr. Schroeder at 407-475-4763.

Sincerely,

Emma R. Singleton
Director, Florida District